K003720
page 1 of 1

JUN 2 7 2002

510 (k) SUMMARY

I. ADMINISTRATIVE

Submitter: Lifestream Purification Systems, LLC
2001 South Lamar, Suite G
Austin, TX 78704
(512) 707-3773

Contact Person: Amy Heilman

Date of Preparation: November 30, 2000

II. DEVICE NAME

Proprietary Name: Angel of Water™

Common Name: Colon Hydrotherapy System

Classification Name: Colonic Irrigation System

III. PREDICATE DEVICES

Jimmy John III (Colon Therapeutics, Inc; K881720)
Libbe Rectal Tube (Tiller Mind and Body, Inc.; K962259)

IV. DEVICE DESCRIPTION

This device is an instrument for hydrotherapy of the colon. It introduces filtered water at a comfortable temperature into the large intestine, thus cleansing the colon of its contents when medically indicated, such as before radiological or endoscopic examination. It is hygienic, comfortable and painless. Water temperature is controlled by means of an audible alarm. Temperature, flow, and pressure are controlled by one switch operated by the user. The system is manually sanitized prior to each use with a suitable broad-spectrum disinfectant. The system includes disposable tubing and a sterile, disposable rectal nozzle intended for single use only.

V. INTENDED USE

For colon cleansing when medically indicated, such as before radiological or endoscopic examination.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2002

Ms. Amy Heilman
General Manager
Lifestream Purification Systems, LLC
2001 South Lamar, Suite G
AUSTIN TX 78704

Re: K003720
Trade/Device Name: Angel of Water™ Colon Hydrotherapy System
Regulation Number: 21 CFR 876.5220
Regulation Name: Colonic irrigation system
Regulatory Class: II
Product Code: 78 KPL
Dated: May 18, 2002
Received: May 20, 2002

Dear Ms. Heilman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K003720

Device Name: Angel of Water™ Colon Hydrotherapy System

Indications for Use:

Colon cleansing when medically indicated, such as before radiological or endoscopic examination.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Steven A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K003720